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# EBU Response to EC Green Paper on mobile health ("mHealth")

**July 2014**

## Introduction

The European Blind Union (EBU) welcomes the opportunity to respond to the European Commission’s Green Paper on mHealth. This is an ideal opportunity to address the issue of accessibility of mHealth products and services. We agree with the Commission’s statement that it is “*imperative to ensure that technology is safe and secure for use by citizens*.” This must of course include citizens that are blind or partially sighted. We are concerned that inaccessible mHealth products and services could render them useless or even harmful to blind and partially sighted people.

We welcome the fact that the rapid spread of smartphones has boosted the use of mobile apps offering healthcare and wellbeing services. Indeed we agree with the Commission that, potentially, the ‘*availability of satellite navigation technologies in mobile devices provides the possibility to improve the safety and autonomy of patients*’. Like the Commission, we also believe that mHealth can ‘*contribute to the empowerment of patients as they could manage their health more actively, living more independent lives in their own home environment thanks to self assessment or remote monitoring solutions’*. **However, empowerment can only take place if mobile health devices and apps are fully accessible to all patients.**

**The European Union ratified the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), which is now is force and binding.** There are specific obligations in relation to accessibility set out in article 9 of the UNCRPD: *'States Parties shall take appropriate measures to ensure to persons with disabilities access, on an equal basis with others, to […] information and communications, including information and communications technologies and systems, and to other facilities and services open or provided to the public […] These measures, which shall include the identification and elimination of obstacles and barriers to accessibility, shall apply to, inter alia […] b. Information, communications and other services, including electronic services and emergency services.*'

New technologies and the Internet have the potential to offer unprecedented opportunities to widen access to information. Unfortunately, as the Commission is aware, the vast majority of websites[[1]](#footnote-2) and applications (apps) continue to be either fully or partly inaccessible to blind and partially sighted people who need assistive technology (such as text-to-speech screen reader and screen magnification software) to access websites and apps; however this can only work if websites and apps are designed in an accessible manner, using recognised web accessibility standards such as the Web Content Accessibility Guidelines 2.0 (WCAG 2.0) and European Standard EN 301 549[[2]](#footnote-3).

Non-binding instruments have failed to deliver accessible websites and online services so we urgently need full and comprehensive legislation to ensure the accessibility of websites, apps and online services in general – this also applies to mHealth products and services.

According to research[[3]](#footnote-4) mentioned in the Commission Green Paper, recent estimates show that 97,000 mHealth apps are currently available across multiple platforms on the global market. If this developing market is left unchecked and unregulated, EBU believes that the vast majority of mobile health apps will be inaccessible to people with sight loss. We believe that mHealth products and services traded in the EU should meet robust accessibility and safety requirements – a robust EU legislative framework that guarantees both access to and safety of these products is therefore needed. While the organisation of healthcare systems is a national or regional competence, harmonisation of the mHealth products and services market is a cross-border issue; it therefore requires coordinated action at EU level to ensure accessibility, safety of the products and services and a level-playing field for manufacturers.

### Why is it so important that blind and partially sighted people can access mHealth products?

#### Access and safety

We are deeply concerned about the fact that the 30 million blind and partially sighted Europeans are not currently able to use many of these products because they are not designed accessibly. More worryingly, many of these products are only partly accessible and may not function as intended, i.e. blind and partially sighted people may not be able to, for example, read important safety information or upload vital technical updates. Because of this, blind and partially sighted people are not only unable to benefit from many of these products but might actually be at increased risk because they are unable to access important information and features in the products. Furthermore, accessibility of mHealth products and services is also important for blind and partially sighted professionals who are working in the health sector - they too must be able to use these products and services and access patient data collected via mHealth devices and apps.

#### Improving equality

We welcome the move to empower patients to take charge of their own health as far as possible by using mHealth products. We believe that many blind and partially sighted people could greatly benefit from improved access to information and health monitoring that mHealth products could provide if they were accessible.

**Blind and partially sighted people already face massive disadvantages in the health system** as they are often unable to detect early signs of illness (such as a noticing a potentially cancerous mole or monitoring themselves for high blood pressure). Blind and partially sighted people also have more difficulty eating healthily and taking regular exercise due the barriers that sight loss creates. For example, buying fresh ingredients and then cooking them from scratch is much more difficult than simply using convenience microwave foods. Simply going for a walk or a run requires planning and often requires a guide. Blind and partially sighted people also have less access to healthcare related information such as medication dosage or instructions about follow up care after leaving a hospital. Health related information is often only made available to patients in print format so it is inaccessible to blind and partially sighted people. In the UK, for example, research shows that blind and partially sighted people are a third more likely to face barriers to accessing healthcare.[[4]](#footnote-5)

Furthermore, many blind and partially sighted people have **multiple conditions** which may be unrelated to their sight condition and having poor vision can compound those additional conditions. In this context, mHealth products may help to overcome some of these barriers by providing easier access to information on healthy living and, for example, dosage instructions or accessible blood pressure tracking. We note that there are a number of apps available to help patients monitor their diabetes such as the newly launched EU funded app for managing diabetes called **GlucoTab® - we would be keen to learn whether this app i**s accessible to blind and partially sighted people, particularly as sight loss and diabetes are linked and therefore a large proportion of people with diabetes have sight loss and would find such an app of great use. [[5]](#footnote-6)

#### Saving money

We believe that the upfront cost of delivering accessible products and services, including websites and apps, can be offset by the social and economic benefits of greater inclusion of persons with disabilities and the generation of substantial savings. Some governments have researched the potential savings that an efficient online service delivery could generate. The UK government’s **Digital Efficiency Report**[[6]](#footnote-7) states that, on the basis of historic data looking at the savings already achieved by existing digital services over offline alternatives, between £1.7 billion and £1.8 billion could be realised as total annual savings as f*or* some government services *‘the average cost of a digital transaction is almost 20 times lower than the cost of a telephone transaction, about 30 times lower than the cost of postal transaction1 and about 50 times lower than a face-to-face transaction.***’** Inaccessible online services lead to the need to maintain and resource alternative channels to access services (e.g. telephone help lines, face to face interaction) which are known to be more expensive to support.

## Responses to questions in the Green Paper

### 1 - Data protection, including security of health data

**Which specific security safeguards in mHealth solutions could help to prevent unnecessary and unauthorised processing of health data in an mHealth context?**

Robust personal data protection is vital to building trust in mHealth solutions therefore EBU believes that mHealth solutions should include specific and suitable security safeguards such as the encryption of patient data and appropriate patient authentication mechanisms to mitigate security risks. However, such systems should not render the products inaccessible for people who use assistive technology to access mHealth products and services. We have often underlined the fact that security of data is just as important for people with sight loss as it is for their sighted peers. However, in our experience most online security systems (e.g. CAPTCHAs[[7]](#footnote-8), ‘Verified by Visa’ and so on) solely rely on visual interaction and accessible alternative are rarely provided so these security features are not accessible to blind and partially sighted people. For more detailed information on this issue, please see our response to the EC Green Paper ‘Towards an integrated European market for card, Internet and mobile payments[[8]](#footnote-9). We therefore believe that it is crucial to prioritise standardisation of security features, to ensure that they are accessible for people who use assistive technology. The need to ensure the interoperability of such systems is also paramount.

Any guidelines developed for safety and security requirements of mHealth applications must be comprehensive and ensure accessibility; mHealth is not a 'stand alone' concept, it is a means to an end, so the relevant authorities responsible for services that will be delivered through mHealth products and services should be overseeing the development of guidelines to that effect, e.g. health authorities should be involved in the development of guidelines for safety and security requirements of health-related applications. In addition it is important to anticipate the evolutions that increasing ‘device to device’ connectivity will deliver in the context of the ‘Internet of Things’. There are opportunities and challenges to be addressed in this context, which are of course also relevant in the context of eHealth and mHealth policy - we outlined some of the key issues to address in our response to the 2012 EC consultation on the Internet of Things[[9]](#footnote-10)**.**

To ensure the security and accessibility of mHealth products and services, the following features must be taken into account:

* **Security features such as authentication and identification systems**. As mentioned above, systems such as CAPTCHAs*[[10]](#footnote-11)* cannot always be used without sight. Some systems also require the user to carry a hardware device such as a number generator, yet there are no talking or alternative accessible versions available.These features remain a major barrier to access for blind and partially sighted users. **Again, we fully understand the need to ensure online security, but the systems put in place can and should be accessible.**
* **Social media content embedded in websites.** Social media is transforming how public authorities engage with citizens, allowing them to share information and deliver services more quickly and effectively than ever before. For example, social media and online forums are increasingly replacing telephone helplines or helpdesk services. When relying on mHealth products and services, public authorities therefore have a **responsibility** to ensure that social media content, data and platforms used in this context are accessible to all, including people with sight loss. There is a clear set of basic social media guidelines for desktop and mobile access that can and should be followed to make sure that social media content is accessible to people who use assistive technologies. Those responsible for designing social media content should therefore ensure that the relevant best practice is applied.
* **User-generated content and** **authoring tools** **used to create such content** and interact with users. Accessible authoring tools are an essential component in achieving an accessible web as they enable the production of accessible web content regardless of the technical knowledge of the content authors.[[11]](#footnote-12)
* **Electronic documents and forms downloadable** from websites. Regrettably, it is often the case that otherwise well designed websites lead to totally inaccessible downloadable documents or forms; it is therefore crucial that open and well tagged document formats are used for text or forms that users need to interact with, whether online or offline.

**How could app developers best implement the principles of “data minimisation” and of "data protection by design, and “data protection by default” in mHealth “apps”?**

All aspects of mHealth products must be made accessible to people with sight loss in order for them to be able to read and agree to privacy settings and enable updates which may be security related. It is possible that in the future mHealth products will be widely used to collect and share health data so data protection issues must be taken seriously. It is therefore extremely important that any warnings, explanation about what data will be shared and ability to request amendments to personal data when using mHealth products and services is made accessible to people with sight loss.

In the Green Paper the Commission refers to the guidance on data protection requirements for 'apps' that the Article 29 Working Party published in its February 2013 *Opinion on apps on smart devices*. The opinion seeks to clarify the legal obligations of each of the parties involved in the development and distribution of apps and highlights the need to provide clear and unambiguous information about data processing to users (e.g. the types of data processed, the purposes for processing and data retention periods) and also states that this information should be made available in a ‘*clear and unambiguous format*’ prior to the installation of the app (e.g. in the description of the app on the app store**). However, we regret that the opinion does not stress the need to make this information fully accessible to people who use assistive technology to access apps and may not therefore provide sufficient advice for app developers.**

We would therefore urge the Commission to raise this issue with the Article 29 Working Party to ensure that any revision of the opinion incorporates the need to make the information fully accessible to people with sight loss. The current revision of the Data Protection Directive also provides an opportunity to address this matter which we are urging the Commission to seize in order to ensure that all citizens are given the same high level of protection as their sighted peers.

### 2 - Big data

**3- What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU whilst complying with legal and ethical requirements?**

We do not have expertise in this area of policy

### 3 - State of play on the applicable EU legal framework

**Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?**

No. Lifestyle and wellbeing apps need to be made fully accessible to all users, including blind or partially sighted people. Without EU accessibility legislation to ensure this, there could be issues with updates not working or safety warnings being unreadable to blind and partially sighted people, putting them at risk.

At the time of writing, there is no EU legislation in place to ensure the accessibility of websites and apps. The European Commission published a proposal on the accessibility of public sector bodies’ websites in 2012, but its very narrow scope will not provide an adequate lever for accessibility unless it is greatly enlarged during the ongoing legislative process. The “Digital Agenda for Europe” promised that the legislation would ensure that ‘all public websites and websites providing basic services to citizens’ would be fully accessible by 2015’, yet the European Commission published a draft directive which falls well short of this commitment. As the organisation representing the group of disabled people most disproportionately affected by barriers to access information, we made our concerns about the content of the draft directive very clear when it was published.[[12]](#footnote-13) These were as follows:

* **The proposal fails to recognise mobile devices and mobile “apps”**, which means many mHealth services would not be covered by this legislation.
* The Directive **only covers 12 services, therefore excluding the vast majority of public services but also key services delivered by private providers, such as commercial mHealth services –** this isa major issue as many mHealth products are currently made by private companies.
* The European Commission **did not include any enforcement provisions** in its proposal, giving blind and partially sighted people no right to redress.

In any case, the Commission proposal was not originally intended to cover the private sector at all. So given the fact that the app market is dominated by small and medium enterprises and individuals (i.e. app developers), the lack of mandated standards on accessibility and interoperability between mHealth solutions and devices is likely to negatively impact outcomes for blind and partially sighted people. Indeed EBU is concerned about the fact that small scale app developers will not necessarily have the relevant skills to ensure the accessibility and interoperability of their products and services and that they may as a result, as outlined by the Commission in the Green Paper, ‘*favour short-term strategies for quick market access’*.

However, we note that following successful negotiations, European Standard EN 301 549 on accessibility requirements for Information and Communication Technologies (ICT) products and services was adopted and published in February 2014. This new standard is the first European Standard for accessible ICT which covers websites, software and digital devices so it does provide the relevant information to help design accessible mHealth products and services. Unlike most standards it is also available free of charge.

New EU Public Procurement rules were adopted on 26 February 2014**. Directive 2014/24/EU on public procurement states that ‘*For all procurement which is intended for use by natural persons, whether general public or staff of the contracting authority, the technical specifications shall (...) be drawn up so as to take into account accessibility criteria for persons with disabilities.’* EBU welcomes the introduction of a mandatory accessibility criterion in public tenders as it will ensure that large scale public procurement of mHealth products will be accessible going forward. However, this legislation only concerns public sector tenders so it will not mandate the accessibility of products and services developed by the private sector, which is currently the main source of mHealth products development.**

There is also growing evidence that divergent policy approaches to web accessibility in EU Member States are fragmenting the digital internal market[[13]](#footnote-14). Over time an increasing number of Member States have taken action to improve web accessibility, including through national legal obligations. It is not clear how many – if any – of these national obligations are covering apps but different requirements and different certification standards incur additional costs for economic operators who work across borders. This creates barriers to trade, impedes growth and stifles innovation.

**We are therefore urging the Commission to publish the promised European Accessibility Act which has been repeatedly delayed since it was announced by Commissioner Reading in 2011.** We need this act to be the robust EU legislative framework that is required to ensure the accessibility of all goods and services, including mHealth goods and services. In our response to the European Commission consultation on the European Accessibility Act[[14]](#footnote-15) we emphasised the need for all ICT products and services to be accessible, as well as information that is related to such goods and services.

In addition, we believe that there is a need to address concerns that health and wellbeing apps designed to aid people in the diagnosis and management of eye conditions could potentially cause harm to patients. Any app that claims to provide ‘advice’ of a medical nature should be screened to ensure that this advice (for example to seek emergency medical help for a sudden change in vision) is appropriate, up-to-date and reliable. We are concerned that at the moment many ‘medical’ apps do not have to be registered, so their content is unchecked.

The eHealth Action Plan 2012-2020[[15]](#footnote-16) mentions the rise of mHealth and the fact that it is blurring the distinction between the traditional provision of clinical care and self-administration of care and wellbeing. EBU therefore welcomes the European Parliament resolution on the eHealth Action Plan 2012-2020[[16]](#footnote-17) which stresses the need to have **a clear legal framework to ensure their development and safe adoption**.

**Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts; if yes, why and how?**

Yes. We are concerned about the fact that there are currently no rules that clearly outline the difference, from a legal point of view, between lifestyle and wellbeing apps and a medical device or in vitro diagnostic medical device. We welcome the fact that the Commission is planning to update its guidance this issue. We understand that the guidance currently states that, depending on their intended purpose, apps may fall under the definitions of a ‘medical device’ or of an ‘*in vitro* diagnostic medical device’ and therefore would have to comply with the relevant provisions in the directives regulating those devices. However, since Commission guidance does not equate to binding rules there is still legal uncertainty that is detrimental to citizens.

EBU therefore believes that the European Commission should review the current EU legislative framework to ensure that it gives adequate protection to citizens and clarifies the binding rules that apply to mHealth apps. This is especially important as the European Court of Justice has not had the opportunity to clarify the applicability of existing EU law to mHealth and wellbeing apps. Failing to address this issue will continue to put the health of EU citizens at risk.

**As such, it is vitally important to ensure that legislation is enacted to make sure that, from the outset, mHealth products are safe and that manufacturers are legally required to make them accessible to blind and partially sighted people.** As outlined above, mHealth products that are not accessible to blind and partially sighted people not only disadvantage them but can also put their health in greater danger because important product information, such as safety warning and updates, may not be available to them.

There is compelling **evidence** from the United States which demonstrates that legislation can be a strong lever to deliver accessibility. Section 508 of the Rehabilitation Actestablishes requirements for electronic and information technology developed, maintained, procured or used by the Federal government. It requires such technology to be accessible to people with disabilities, including employees and members of the public. It is the pressure of educational authorities in the US that led APPLE to mainstream accessibility features such as voice over technology in all its products, including the *Iphone* and the *Ipad*. The same argument led AMAZON to mainstream voice output features in its *Kindle 2* ebook reader, following legal action over the fact that the original *Kindle* device was inaccessible for blind students. Likewise, all GOOGLE *Android* products (e.g. operating systems in mobile phone, TV sets, etc.) now have “talk back” features built in.

### 4 - Patient safety and transparency of information.

**What good practices exist to better inform end-users about the quality and safety of mHealth solutions (e.g. certification schemes)?**

As outlined above, all aspects of mHealth products must be made accessible to blind and partially sighted people. For example, whether the app has been approved under a specific certification scheme; if this does not happen then blind and partially sighted people would be at risk of using unsafe products. In addition, the safety warnings in apps are often displayed as ‘pop up’ warnings which are frequently inaccessible to access technology and therefore impossible to read for blind and partially sighted people.

The Green paper makes reference to the National Health Service online Health Apps library in the United Kingdom, where all apps have passed a review to prove their safety and compliance with data protection rules. Those Patient Decision Aids (PDAs)[[17]](#footnote-18) are also being tested for accessibility for blind and partially sighted people to ensure that they can be used by the largest amount of citizens possible and to ensure that blind and partially sighted people can be confident that any PDAs they use from that website will be accessible to them. We believe that all mHealth apps should be similarly screened for accessibility.

We also think that working with organisations of people with disabilities is the only way to achieve successful outcomes when designing accessible solutions. In Denmark, for example, the introduction of digitalization of communications between citizens and public authorities has led to a solution, NemID[[18]](#footnote-19), which included accessibility features (e.g. large print code cards to ensure maximum security for citizens with low vision) from the outset. Though some barriers to accessibility remain (e.g. inaccessible online forms and PDFs), the way NemID was developed demonstrated the value of ongoing dialogue between users, organisations of disabled people, developers and public authorities in order to deliver better accessibility for all.

**Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?**

We are concerned that some mHealth solutions may not function as expected or may not have been properly tested and may therefore endanger people's lives.

As outlined previously, comprehensive legislation must be enacted to ensure the accessibility - and therefore safety - of all mHealth products for blind and partially sighted people. This must be underpinned by standards that are specific to the sector and there must also be a robust monitoring mechanism to ensure that the medical information content of mHealth products and services is accurate, up-to-date and safe. Furthermore, the effectiveness of mHealth solutions should be evaluated by public health authorities to ensure that they provide the expected health benefits. This can only be achieved through adequate involvement of Member States health services and robust supervision.

**How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?**

As outlined above, comprehensive legislation must be enacted to ensure the accessibility - and therefore safety - of all mHealth products for blind and partially sighted people. This must include the guarantee that accessible information will be available to blind and partially sighted people who want to use mHealth solutions and as outlined above, regular monitoring of the health information content that the products include by the relevant health authorities.

We are concerned that unless appropriate reviews are carried out, the information these solutions provide could be insufficient or even dangerous as the app developer may not have followed established medical guidelines or clinical tests. In addition, we are concerned about the fact that some patients may be at risk if using an mHealth product incorrectly leads them to believe that they are healthy.

Safety could perhaps be supported by user safety standards or quality labels but users should be made aware that the use of mHealth products should never be a substitute for regular medical checks by a qualified doctor.

### 5 - MHealth role in healthcare systems and equal access

**Do you have evidence on the uptake of mHealth solutions within EU's healthcare systems?**

We have anecdotal evidence of uptake of mHealth solutions – as outlined above – but no quantitative data about the level of uptake.

**What good practices exist in the organisation of healthcare to maximise the use of mHealth for higher quality care (e.g. clinical guidelines for use of mHealth)?**

See our response above in relation to PDAs being tested for accessibility in the UK.

**Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?**

No, but we acknowledge that with the right support and safeguards in place, mHealth solutions have the potential to curb health monitoring costs as well as to empower people to look after their own health. In principle, we agree with the Commission about the fact that ‘*mHealth can contribute to a more equitable access to healthcare as technologies spread to remote areas and people that would otherwise not have easy access to healthcare’*. Indeed, as stated in the Green Paper, mHealth could also help facilitate access to healthcare for people with disabilities, especially if they find it difficult to visit a doctor because of mobility issues. But again, for this to actually happen it is crucial to ensure that mHealth products and services are accessible to people who need assistive technology to access these products and services.

**What policy action could be appropriate at EU, as well as at national, level to support equal access and accessibility to healthcare via mHealth?**

As outlined above, comprehensive EU legislation must be enacted to ensure the accessibility and safety of all mHealth products for blind and partially sighted people - mHealth products should also be interoperable with existing and developing technology, including assistive technology used by disabled people in the EU. This must be emphasised because blind and partially sighted people routinely use a wide range of assistive technologies (e.g. screen readers, screen magnifiers, refreshable Braille displays, etc.) so interoperability between new mHealth products and assistive technologies should be a priority. Furthermore mHealth service providers should ensure that they present information in an accessible manner and therefore avoid inaccessible tables, graphics and so on.

### 6 - Interoperability

**What, if anything, do you think should be done, in addition to the proposed actions of the eHealth Action Plan 2012-2020, in order to increase interoperability of mHealth solutions?**

The lack of interoperability of mHealth solutions is likely to be a major issue for disabled people who use assistive technology. Unfortunately, the eHealth Action Plan 2012-2020 makes no mention of this issue, nor does it acknowledge the specific needs of patients with disabilities. There are 80 million people who live with a disability in the EU and 30 million who live with sight loss. The prevalence of disability, including sight loss, increases with age and the EU population is ageing. Forecasts indicate that older people will be in the majority in EU countries by the year 2025. According to Eurostat[[19]](#footnote-20), the share of those aged 80 years or above in the EU-27 population is projected to almost triple between 2010 and 2060. An increasingly ageing population will mean that more and more people will live longer and experience disability at some stage in their lives so the accessibility of mHealth products and eHealth in general must be addressed. The absence of standards mandating interoperability between mHealth solutions and devices is a major concern to us as it will prevent blind and partially sighted people from using mHealth products and services. Given what is at stake, we believe that the European Commission should mandate a range of standardisation initiatives to ensure that mHealth products and services are accessible to all and that there is a level playing field for manufacturers of mHealth solutions.

We welcome the fact that some European standardisation organisations are beginning to work on standards for mHealth products and services. However, progress is slow and we are concerned about the fact that SMEs and individuals app developers who dominate the mHealth app market, may not take those standardisation initiatives into account.

Furthermore, we believe that the European eHealth Stakeholder Group should include representatives of organisations of disabled people. EBU would therefore like the Commission to proactively seek candidates from such organisations when membership of the group is renewed. Given the specific accessibility issues that people with sight loss experience when trying to access information, we believe that the group should include a sight loss expert with the relevant technical expertise to advise the Commission.

**Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records? And if yes by whom and how?**

While this may not the most pressing need from the patient’s point of view, interoperability in this area would also be welcome. As mentioned above, issues around data protection would of course have to be addressed at the same time.

### 7 - Reimbursement models

**Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?**

We do not have information about this.

**What good practice do you know of that supports refund of mHealth services (e.g. payer reimbursement model, fee-for-a service model, other)? Please give evidence.**

We do not have information about this

### 8 - Liability

**What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?**

We are concerned that there could be damage to patient health caused by unregulated mHealth solutions. The risks are numerous: the device could have a defect, a wrong diagnosis could be based on inaccurate data; the patient may not use the device correctly. App developers, mHealth manufacturers and healthcare professionals need legal certainty regarding the liability risks that they may face if the use of a mHealth product lead to damage to a patient’s health. EBU believes that clarification of liability will provide manufacturers with legal certainty and ultimately ensure greater patient safety. Liability issues should therefore be addressed in the future regulatory framework of mHealth products.

### 9 - Research and innovation in mHealth

**Could you provide specific topics for EU level research & innovation and deployment priorities for mHealth?**

We would welcome research & innovation in the field of mHealth related to eye health and prevention of sight loss, as well as monitoring of conditions associated with sight loss. We welcome the fact that mHealth funding will continue under Horizon 2020 and that it will prioritise mobile technologies and applications for ‘integrated, sustainable, citizen-centred care’. We want developers to ensure that their research is taking on board the expertise of blind and partially sighted people when new products are developed and tested.

Lastly, we believe that EU funding for mHealth products and services should only be granted on the condition that such products and services are accessible to all.

**How do you think satellite applications based on EU navigation systems (EGNOS and Galileo) can help the deployment of innovative mHealth solutions?**

Satellite navigation systems can add significant features to apps that many people find extremely useful, including blind and partially sighted people. For example, there are apps using GPS location that people with sight loss can use to travel independently. Such apps have considerably increased the autonomy of people with sight loss so there is significant potential for similar features to deliver useful similar outcomes in the field of mHealth.

### 10 - International cooperation

**Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?**

We welcome international cooperation in the area of mHealth but would like to ensure that the interests of patients are protected. In short, the European Commission should ensure that international accessibility and interoperability standards for mHealth are fit for purpose. Greater market growth and the race for market share in mHealth products and services should not happen at the expense of patient safety; the European Commission should therefore ensure that regulatory convergence is not a ‘race to the bottom’.

**Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?**

We do not have information about these markets.

### 11 - Access of web entrepreneurs to the mHealth market

**Is it a problem for web entrepreneurs to access the mHealth market? If yes, what challenges do they face? How can these be tackled and by whom?**

If the regulatory framework ensures that mHealth products and services are accessible and safe for all to use, then this may not be a problem. We note that the eHealth Action Plan 2012-2020 includes actions that support web entrepreneurs, including networking of so-called ‘European high-technology accelerators’ to give advice and training to eHealth start-ups. However, we would like reassurance from the Commission that such training would include disability awareness and highlight the importance of accessibility.

**If needed, how could the Commission stimulate industry and entrepreneurs involvement in mHealth, e.g. through initiatives such as "Startup Europe" or the European Innovation Partnership on Active and Healthy Ageing?**

As mentioned above, EU funding schemes could stimulate involvement and innovation in this market but we believe that such funding should only be granted on the condition that the mHealth products are made accessible to all.

## Conclusion

We believe that mHealth products and services can usefully contribute to improving the health and well being of EU citizens. However, in a context of rapid technological development, **the legislative framework needs to be robust in order to provide a level-playing field for manufacturers as well as accessibility and safety for consumers**.

We therefore look forward to the adoption of legislative acts that will ensure that mobile health is fit for purpose and does not exclude patients with disabilities because of the way devices and apps are designed. **We take this opportunity to highlight the need for urgent publication of a comprehensive European Accessibility Act and speedy completion of legislative work on the Directive on the accessibility of public sector bodies' websites.** We also hope that thenew EU Public Procurement rules will be swiftly transposed in Member States, ensuring that mobile health products and services that are publicly procured are fully accessible.

Also important is the need to have a legislative framework that is future-proof as technology development is moving apace. The regulatory framework should ensure that there is no disconnect between the mHealth products and services developed and the assistive accessibility that disabled people need to use them. Failing to address the regulatory and standardisation challenges that this entails would be failing the 30 million EU citizens who live with sight loss – a figure that is set to grow as the EU population ages. There is therefore a compelling case for the regulation of mHealth products and services to ensure that that they are both accessible and safe for all.

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## About us

The **European Blind Union (EBU)** is a non-governmental, non profit making European organisation founded in 1984. It is one of the six regional bodies of the World Blind Union, and it promotes the interests of blind people and people with low vision in Europe. It currently operates within a network of 44 national members including organisations from 27 European Union member states, candidate nations and other major countries in geographical Europe.

**Our Interest Representative Register ID is 42378755934-87**

We are happy for our contribution to be made public

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1. In 2008 the European Commission published a study highlighting that only 5.3% of government websites were accessible. See: MeAC Study 2008 <http://www.eaccessibility-progress.eu/wp-content/uploads/2008/04/meac_report_06_11_final.pdf> While a recent European Commission study claims that there has been some limited progress in this area, it also says that there remains ‘*much room for improvement*’. See: <http://ec.europa.eu/digital-agenda/en/news/study-assessing-and-promoting-e-accessibility> [↑](#footnote-ref-2)
2. <http://www.etsi.org/index.php/news-events/news/754-new-european-standard-on-accessibility-requirements-for-public-procurement-of-ict-products-and-services> [↑](#footnote-ref-3)
3. Research2Guidance (2013), "*The mobile health global market report 2013-2017: the commercialisation of mHealth apps*" (Vol. 3). [↑](#footnote-ref-4)
4. Sally McManus and Chris Lord, “Circumstances of people with sight loss - secondary analysis of Understanding Society and the Life Opportunities Survey” Royal National institute of Blind People 2012. [↑](#footnote-ref-5)
5. <https://ec.europa.eu/digital-agenda/en/news/technology-supports-diabetic-patients-and-their-doctors> [↑](#footnote-ref-6)
6. <http://publications.cabinetoffice.gov.uk/digital/efficiency/digital-efficiency-report.pdf> [↑](#footnote-ref-7)
7. <http://en.wikipedia.org/wiki/CAPTCHA> [↑](#footnote-ref-8)
8. <http://www.euroblind.org/media/position-papers/EBU-Response-to-EC-Green-Paper-epayments-Final.doc> [↑](#footnote-ref-9)
9. <http://www.euroblind.org/media/position-papers/EBU-RESPONSE-EC-CONSULTATION-ON-THE-INTERNET-OF-THINGS.doc> [↑](#footnote-ref-10)
10. <http://en.wikipedia.org/wiki/CAPTCHA> [↑](#footnote-ref-11)
11. For more information on authoring tools and accessibility, see <http://www.w3.org/standards/agents/authoring> [↑](#footnote-ref-12)
12. [EBU press release on Commission proposal for accessibility of public sector bodies websites 05/12/12](http://www.euroblind.org/media/press-releases/EBU_press_release_05-dec_2012.doc) [↑](#footnote-ref-13)
13. See 2009 G3ICT White Paper ‘Web accessibility Policy Making, an International Perspective’(<http://bit.ly/lTlRNP>) and 2009 European Commission study on ‘Web accessibility in European countries: level of compliance with latest international accessibility specifications, notably WCAG 2.0, and approaches or plans to implement those specifications’. (<http://bit.ly/913VyJ> -See Annex II, “Overview of Accessibility Related Obligations Imposed on Website Owners in Selected Member States & of National Sources of Data on Compliance”) [↑](#footnote-ref-14)
14. <http://www.euroblind.org/media/position-papers/EBU_response_consultation_European_Accessibility_Act_2012.doc> [↑](#footnote-ref-15)
15. <http://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century> [↑](#footnote-ref-16)
16. <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0010+0+DOC+XML+V0//EN> [↑](#footnote-ref-17)
17. See <http://www.rightcare.nhs.uk/index.php/shared-decision-making/about-the-pdas> [↑](#footnote-ref-18)
18. <http://en.wikipedia.org/wiki/NemID> [↑](#footnote-ref-19)
19. <http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Population_structure_and_ageing> [↑](#footnote-ref-20)